

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B-14813 PCT	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/B2004/003385	International filing date (day/month/year) 15.10.2004	Priority date (day/month/year) 27.10.2003	
International Patent Classification (IPC) or national classification and IPC A61M5/142, F04B7/06, F04B19/00			
Applicant ECOLE POLYTECHNIQUE FEDERALE DE LAUSANNE (EPFL)			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 11.03.2005		Date of completion of this report 23.12.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer  Michels, N Telephone No. +31 70 340-4025	



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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-13 as originally filed

**Claims, Numbers**

1-18 as originally filed

**Drawings, Sheets**

1/6-6/6 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-4, 6-18

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-4,6-18 are so unclear that no meaningful opinion could be formed (*specify*):

**see separate sheet**

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	5
	No: Claims	
Inventive step (IS)	Yes: Claims	5
	No: Claims	
Industrial applicability (IA)	Yes: Claims	5
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

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**Re Item III.**

The application does not meet the requirements of Article 6 PCT, because claims 1 - 4, 6 - 18 is not clear to such an extent that a meaningful examination of these claims is not possible at this stage (see for detailed reasoning Item VIII).

**Re Item V.**

- 1 Claim 5 comprising the features of claims 1 - 3 and the cavity portion (disclosed on page 11, lines 22 - 28) meets the requirements of PCT Article 33(2) and (3).

- 1 The following documents are referred to in this communication:

D1 : US 4 883 467 A (FRANETZKI MANFRED ET AL) 28 November  
1989(1989-11-28)

- 2 Document D1, which is considered to represent the most relevant state of the art, discloses (see column 4, line 17 - column 7, line 68; the references in parentheses applying to this document):  
a micro - dosing reciprocating pump (201) having a pump chamber (207), a fluid inlet (211), an axially movable piston (237) forming a gap (247) with the pump cylinder (245), which provides fluid communication between the pump chamber and the inlet, magnetic coils (253, 255) for axially driving the piston against a restoring (spring or magnetic) force and a fluid outlet chamber (259) comprising a magnetic closing element (263) and seal disc (265).

From this, the subject-matter of independent claim 5 differs in that the rotor (32) is magnetically driven axially for pumping and rotatively at the same time for controlling the opening and closing phases of the fluid inlet and outlet valves composed of the angled seal rings (54, 56) and the grooves in the axle extensions (46, 48).

- 2.1 The subject-matter of claim 5 is therefore novel (Article 33(2) PCT). The problem to

be solved by the present invention may be regarded in that for a more simple design is looked in order to reduce size as well as a less complex design allowing the drug administration to be more accurate and more reliable.

- 2.2 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) in that the rotation and translation of the rotor in combination with the arrangement of the sealing rings, which act as bearings and valve members at the same time, results in a reduction of pump components. The design seems to have an increased reliability in regard to wear induced failure and a reduced degree of complexity in the design. Additionally the stroke volume being in the range of nanoliters per revolution allows a high degree of precision in dosing the drug.

**Re Item VII.**

- 1 According to the requirements of Rule 11.13(m) PCT the same feature shall be denoted by the same reference sign throughout the application. This requirement is not met in view of the use of reference sign 64 on page 11, line 24 (cavity portion) and page 12, line 22 (position sensor).
- 2 According to the requirements of Rule 11.13(l) reference signs not appearing in the description shall not appear in the drawings, and vice versa. This requirement is not met in view of the reference sign 34 (see page 8, line 31) as well as for reference sign 40 on page 9, line 19 and page 10, line 28 (inlet channel) .

**Re Item VIII.**

- 1 The application does not meet the requirements of Article 6 PCT, because claim 1 is not clear insofar as the features of claim 1 do not result in a pump (see also PCT Guidelines chapter 5.54 and 5.55).
- 1.1 It is clear from the description on page 3, lines 14 to 25, page 9, line 13 to page 10, line 24 that the following features are essential to the definition of the invention and to be introduced in claim 1:
  - (1) first and second extensions (46,48) having fluid channels (50, 52) providing fluid communication between each of the extensions with the chamber (32)
  - (2) fluid channels are arranged in the form of grooves extending axially on the surface of the extensions
  - (3) first and second sealing rings (54,56) mounted around the first and second extensions at an oblique angle with respect to a plane perpendicular to the axis of rotation for establishing or preventing fluid communication between the chamber and the extensions according to the angular and axial position of the rotor.
  - (4) cavity portion (64) formed in the stator housing lodging the second (outlet) extension (48)

Since independent claim 1 does not contain these features it does not meet the requirement following from Article 6 PCT that any independent claim must contain all the technical features essential to the definition of the invention.